REMARKS

This Amendment, filed in reply to the Office Action dated March 19, 2008, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 1-30 are all the claims pending in the application. Claims 7-23 and 28-30 are withdrawn from consideration. Claims 1-6 and 24-27 are rejected. Claim 1 is amended herewith to recite that the replication-deficient retroviral vector "is derived from Moloney murine leukemia virus." Support for this amendment can be found throughout the specification as originally filed, and at, for example, page 6, line 5, and is also inherent in Applicants' working examples. Claim 24 is canceled without prejudice or disclaimer. Claims 25-27 are amended to correct antecedent basis in view of the cancellation of Claim 24. No new matter is added by way of this amendment. Entry and consideration of this amendment are respectfully requested.

Priority

Applicants thank the Examiner for acknowledging Applicants' claim to foreign priority and receipt of the certified copies of the priority documents.

Information Disclosure Statements

Applicants thank the Examiner for returning a signed and initialed copy of the PTO Form SB/08 that accompanied the Information Disclosure Statement filed December 4, 2006.

However, on page 2 of the Office Action, the Examiner asserts that the Information Disclosure Statements filed July 10, 2006, and November 9, 2006, fail to comply with 37 C.F.R. 1.98(a)(3)(ii).

Regarding Japanese Application No. JP 2001-520009, which was scored through on the copy of the PTO Form SB/08 returned by the Examiner, Applicants submit herewith a new Information Disclosure Statement, citing the corresponding PCT publication, namely WO 1999/019472, the disclosure of which is the same as that of JP 2001-520009. Thus, WO 1999/019472 constitutes a concise explanation of relevance for JP 2001-520009.

Regarding Japanese Application No. JP 2002-176880, the English language abstract of which was previously considered by the Examiner, Applicants submit herewith the publication of the counterpart U.S. application, namely U.S. Patent Application Publication No. 2005/022260, the disclosure of which is the same as that of JP 2002-176880. Thus, U.S. Patent Application Publication No. 2005/022260 constitutes a concise explanation of relevance for the entire JP 2002-176880 document.

However, regarding the remainder of the references listed on the PTO Forms SB/08 submitted July 10, 2006, and November 9, 2006, Applicants respectfully remind the Examiner that, pursuant to 37 CFR § 1.98, English language translations of foreign language documents *are not required to be filed unless they have been reduced to writing* and are actually translations of what is contained in the non-English language information. Rather, as translations were not available, Applicants note that the Information Disclosure Statements filed July 10, 2006, and November 9, 2006, fully comply with 37 C.F.R. 1.98, since a concise explanation of relevance for each non-English language document was provided for *each* document on the respective Information Disclosure Statements.

Specifically, regarding the PTO Form SB/08 submitted with the Information Disclosure Statement filed July 10, 2007, the references listed therein were cited in a communication from a Foreign Patent Office, and Applicants submitted therewith an English language version of the

communication, indicating the degree of relevance found by the Foreign Patent Office. Accordingly, such satisfies the requirement to submit a concise explanation of relevance. See MPEP § 609.04(a).

Regarding the PTO Form SB/08 submitted with the Information Disclosure Statement filed July 10, 2007, a concise explanation of the relevance of each document was provided in the Information Disclosure Statement, with the exception of JP 2001-520009. As noted above, for this document, Applicants submit herewith a new Information Disclosure Statement, citing the corresponding PCT publication, namely WO 1999/019472, the disclosure of which is the same as that of JP 2001-520009.

In view of the foregoing, the Examiner is requested to return signed and initialed copies of the PTO Forms SB/08 that accompanied the Information Disclosure Statements filed July 10, 2006, and November 9, 2006, acknowledging consideration of all the documents listed therein, with the exception of JP 2001-520009.

Drawings

On page 3 of the Office Action, Figure 3 is objected to for being of improper form. Specifically, the Examiner asserts that Figure 3 lacks a numerical identifier.

In response, Applicants submit herewith a revised Figure 3 containing the appropriate numerical identifiers, thus overcoming the objection.

Withdrawal of the objection is respectfully requested.

Claims 1-6 and 24-27 are Patentable Under 35 U.S.C. § 102

1. On page 3 of the Office Action, Claims 1-6 and 24 are rejected under 35 U.S.C. § 102(e) as being anticipated by Sang *et al.* (U.S. Patent Application Publication No. 2005/0273872), as evidenced by Kamachi *et al.* (*Development*, 1998, 125:2521-2532).

In making the rejection, the Examiner asserts that Sang *et al.* disclose the generation of transgenic avians, expression of transgene-encoded protein within avian eggs, and that replication defective vectors, such as ALV, and other lentiviruses, may be employed to deliver the transgene. The Examiner further asserts that Sang *et al.* specifically disclose obtaining fertile hen eggs containing developing chick embryos at developmental stages X-XIII, and injection of VSV-G peudotyped lentiviral vectors into the subgerminal cavity below the embryo, resulting in GO transgenic chickens.

With specific regard to Claims 2 and 3, the Examiner appears to suggest that the chick embryos disclosed by Sang *et al.* include the gastrula stage, that is, up to and including 48 hours. Such is allegedly evidenced by Kamachi *et al.*, who describe expression of the lens-specific crystallin gene in the developing chicken.

With specific regard to Claim 6, the Examiner contends that Sang *et al.* disclose the analysis of G1 transgenic birds, and transmission of the transgene to G2 progeny from founder birds. With specific regard to Claim 4, the Examiner contends that Sang *et al.* disclose that the transgene may be that which encodes any of a large number of proteins, including sequences encoding antibodies. In view of the above, the Examiner asserts that Sang *et al.* anticipate Claims 1-6 and 24.

Applicants respectfully disagree, and traverse the rejection in view of the following remarks.

Initially, Applicants respectfully point out that Claim 1 is amended herewith to recite that the replication-deficient retroviral vector "is derived from Moloney murine leukemia virus." Support for this amendment can be found throughout the specification as originally filed, and at, for example, page 6, line 5, and is inherent in Applicants' working examples.

Applicants note that "[a] claim is anticipated *only* if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (Emphasis added.) *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir 1987). In the context of anticipation of product-by-process claims, a claimed product may *only* be anticipated by a prior art reference that discloses *the same* product. In this regard, Applicants note that the lentivirus employed in the working examples of Sang *et al.* was Equine Infectious Anaemia Virus (EIAV), which is distinct from the replication-deficient vector derived from Moloney murine leukemia virus, as is recited in Claim 1 as amended. Applicants respectfully submit that the instant claims are not anticipated by Sang *et al.* at least in view of the different vectors employed for transgene delivery, which in themselves impart structural differences to the claimed transgenic bird. Specifically, the claimed transgenic bird is distinguished over that of Sang *et al.* at least due to the stable integration of the Moloney murine leukemia-specific sequences in the delivery vector into the avian genome. Thus, the process limitations of Claim 1 impart structural limitations on the claimed transgenic bird, which are not disclosed by Sang *et al.* Accordingly, the claimed product is *not* the same as that disclosed by Sang *et al.*, as is required to maintain a finding of anticipation. Indeed, Applicants note that on page 3 of the Office Action, it is asserted that "[t]he structural elements of the transgenic chicken, specifically that it possesses a replication defective retroviral vector encoding a desired protein are given patentable weight."

Furthermore, although the Examiner cites to paragraphs [0013] and [0017] of Sang *et al.*, which allegedly disclose replication defective vectors, such as ALV and other lentiviruses, Applicants note that the *only* transgenic avians produced by Sang *et al.* use EIAV vectors. As discussed above, these transgenic avians are not the same as those instantly claimed.

Nevertheless, even if the Examiner relies upon the generic disclosure in paragraphs [0013] and [0017], as indicated on page 4 of the Office Action, Applicants note that these disclosures pertain solely to lentiviruses, and for the reasons mentioned above, do not anticipate the claims. Indeed, the only disclosure of Moloney murine leukemia virus by Sang *et al.* is in paragraph [0016], in which Sang *et al.* state that the use of a delivery vector derived from Moloney murine leukemia virus during development leads to gene silencing, and "very low expression of the transgene," and that "it is therefore essential that any viral vector used for production of transgenic birds does not exhibit gene silencing." See paragraph [0016]. Thus, even if the skilled artisan were to rely upon this passing disclosure, and utilize Moloney murine leukemia virus in the methods disclosed by Sang *et al.*, the transgenic avian obtained would not be *the same* as that currently claimed, as is required to maintain a finding of anticipation, due to the silencing of the transgene. Specifically, the transgenic avians would contain considerably less transgene-encoded protein than those instantly claimed. Accordingly, such a transgenic avian also does not anticipate the claimed product for this reason. Indeed, Applicants respectfully point out that by choosing the appropriate time frame to introduce a transgene into a bird embryo, as is an aspect of Applicants' claimed invention, successful transgene expression can be achieved using Moloney murine leukemia virus, which normally would induce gene silencing.

Accordingly, in view of the above remarks, Applicants respectfully submit that the claims are not anticipated by Sang *et al.*

Withdrawal of the rejection is respectfully requested.

2. On page 5 of the Office Action, Claims 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Ransohoff *et al.* (U.S. Patent Application Publication No. 2003/0176660).

The Examiner asserts that the structural elements of the transgenic chicken egg, specifically, that it possesses various amounts of a desired protein are given patentable weight, but that the source of the eggs, i.e. the transgenic hen producing the egg, or the method of producing the transgenic hen, are not afforded patentable weight. The Examiner asserts that equivalent transgenic egg products may be obtainable from transgenic hens produced by different methods.

In making the rejection, the Examiner asserts that Ransohoff *et al.* disclose compositions containing avian-derived transgenic non-avian antibodies, and methods of recovering the antibodies from transgenic avian eggs. The Examiner further contends that Ransohoff *et al.* disclose that a transgenic chicken egg contains at least 10 mg of human antibody per egg. In view of the above, the Examiner contends that Ransohoff *et al.* anticipates Claims 25-27.

Applicants respectfully disagree, and traverse the rejection in view of the following remarks.

Initially, for reasons discussed above under the rejection over Sang *et al.*, Applicants respectfully submit that the claimed product is distinguished over that of Ransohoff *et al.* at least due to the integration of the Moloney murine leukemia-specific sequences in the delivery vector,

and which are stably integrated into the avian genome, and thus necessarily present within Applicants' egg as claimed. Thus, the process limitations of Claim 1 impart structural limitations on the claimed product, which are not disclosed by Ransohoff *et al.* Accordingly, the claimed product is *not* the same as that disclosed by Ransohoff *et al.*, as is required to maintain a finding of anticipation of a product-by-process claim. Applicants respectfully submit that Ransohoff *et al.* does not anticipate the claims for at least this reason.

Further Applicants' note that neither a Moloney murine leukemia virus-derived vector, nor a G1 transgenic bird, which are important constituents of the invention in amended Claims 1-6 and 25-27, are disclosed by Ransohoff *et al,* thus Ransohoff cannot disclose the same product as that claimed for the above reasons.

Further still, Applicants respectfully submit that Ransohoff *et al.* is not valid anticipatory prior art at least because it lacks an enabling disclosure to produce an egg containing the claimed amount of transgene-encoded protein. The Examiner is reminded that "the disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation." (Emphasis added.) *Elan Pharm., Inc. v. Mayo Found. For Med. Educ & Research*, 346 F3.d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003). Applicants note that Ransohoff *et al.* provide no guidance whatsoever to the skilled artisan as to how to produce an egg encompassed by the instant claims. Indeed, the disclosure of Ransohoff *et al.* is directed entirely to methods for purifying antibodies, and provides no guidance on how to engineer animals to produce an egg containing any transgene-encoded protein, let alone an egg containing a transgene-encoded protein at a concentration within the range claimed by Applicants.

Accordingly, in view of the above remarks, Applicants respectfully submit that the claims are not anticipated by Ransohoff *et al.*

Withdrawal of the rejection is respectfully requested.

Obviousness Type Double Patenting

1. On page 6 of the Office Action, Claims 1-6 and 24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 6-10 and 22 of copending U.S. Patent Application No. 10/569,268.

As this rejection is merely provisional in nature, Applicants request that the rejection be held in abeyance until such time as allowable subject matter is identified.

2. On page 7 of the Office Action, Claims 1-6 and 24-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 41, 44-47 and 49-56 of copending U.S. Patent Application No. 10/523,191.

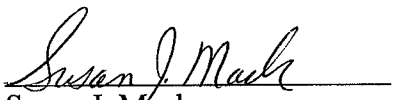
As this rejection is merely provisional in nature, Applicants request that the rejection be held in abeyance until such time as allowable subject matter is identified.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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